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PHARMACIA & UPJOHN
7000 Portage Road
KZO-300-104
KALAMAZOO, MI 49001

EXAMINER

GRASER, JENNIFER E

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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06/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/767,809

Applicant(s)

DOMINOWSKI ET AL.

Examiner

Jennifer E. Graser

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-51 is/are pending in the application.
- 4a) Of the above claim(s) 14-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment and entry of the Amendment submitted on 3/5/07 is made. Claims 1 and 3-13 are currently under examination. Claims 14-51 were previously withdrawn from consideration because they are drawn to a non-elected invention.

Claim Rejections - 35 USC § 112-Written Description

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 3-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to recite that the p68 antigen 'lacks the signal sequence'. However, support for this new language/limitation cannot be found anywhere in the originally filed specification. The sequence listing also fails to describe which amino acids represent the signal sequence. Applicants must point to specific written support for this new limitation by page and line number or remove the limitation from the instant claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1645

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 4, 5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Charles et al (WO 92/17587).

Charles et al teach the isolation of the native P68 antigen of *Bordetella bronchispetica*. Pages 1-6 teach the recombinant production of this polypeptide. Page 6, line 7, specifically teaches that *E.coli* may be used as a host cell. Page 7 teaches the use of this protein in a vaccine composition. Page 7, lines 30-34 teach that an adjuvant may be added to the vaccine composition. Aluminum hydroxide is specifically recited in line 34. The reference specifically recites that the vaccine is for *veterinary* use. Page 1, lines 5-6, teach that *B.bronchispetica* is a bacterial pathogen associated with respiratory disease in animals. The amino acid sequence taught by the reference is identical to that which is recited in SEQ ID NO:1. Although Charles et al do not specifically recite that the vaccine may be used to protect dogs against *B.bronchispetica*, The term “vaccine, effective to protect dogs against *Bordetella bronchispetica*” is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The vaccine composition recited by Charles et al is structurally identical to that recited in claims 1, 3, 4, 5 and 9, and therefore it would be capable of performing the intended use. The signal sequence

Art Unit: 1645

would have inherently been cleaved by signal peptidase when produced recombinantly after the protein was transported.

Response to Applicants' Arguments:

Applicants argue that Charles et al do not teach the intent to vaccinate dogs which is a limiting feature of claim 1. They argue that a recombinantly produced p68 antigen vaccine 'for dogs' is not taught. Applicants argue that 'vaccine' is not solely a word that adds an element to the claims, but it must impart some type of protection to the host. These arguments have been fully and carefully considered but are not deemed persuasive. The product instantly claimed is structurally identical to the product taught by Charles et al. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A patent for a new method/use of a known product may be obtained, but a patent cannot be obtained for a known product, e.g., when the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). The discovery of a new use for an old structure

Art Unit: 1645

based on unknown properties of the structure might be patentable to the discoverer as a *process* of using. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) (Claims 1 and 6, directed to a method of effecting nonaddictive analgesia (pain reduction) in animals, were found to be anticipated by the applied prior art which disclosed the same compounds for effecting analgesia but which was silent as to addiction. The court upheld the rejection and stated that the applicants had merely found a new property of the compound and such a discovery did not constitute a new use) . "While the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition." 363 F.2d at 934, 150 USPQ at 628 (emphasis in original).). The composition taught by Charles et al was taught as a veterinary vaccine to be used in animals.

Applicants additionally argue that Charles et al did not teach isolation of the protein from the cell, e.g., that it was still attached via the signal peptide to the surface of the cell. This has also been fully and carefully considered but is not deemed persuasive. Charles et al teaches the full-length amino acid of the p68 antigen and teaches in great deal how to express the protein recombinantly in *E.coli* or other suitable host cell. The reference specifically teaches isolation and purification of the p68 protein once it is expressed by the cell. See page 2-3

and page 6 with isolation from the transformed host cell mentioned at line 34. The top of page 7 teaches that the proteins may be expressed in heterologous host cells and that it is purified and may be refolded, if needed, following the use of guanidium hydrochloride as denaturant in a conventional manner. It is specifically taught that this **isolated** protein may be used as a veterinary vaccine to be administered to an animal. See page 7, lines 16-35. It is noted that the instant specification allows for the use of both native p68 proteins, i.e., naturally occurring purified or recombinantly produced p68 proteins. See page 7, lines 24-26. The recombinant production methods recited in the instant specification at page 7, lines 27-35, do not in any manner differ from the recombinant production methods taught by Charles et al. Accordingly, the polypeptides in the instant vaccines would be identical to those of the prior art. Lastly, the Experimental Vaccine used in the working examples methods in Example 5 of the instant specification use a native p68 antigen with no mention of the signal peptide being cleaved. Written support for 'lacks the signal sequence' could not be found in the originally filed specification. See written description rejection set forth above.

5. Claims 1, 3, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Montaraz et al (Infection and Immunity, 1985, 47: 744-751).

Montaraz et al teach the isolation of the native P68 antigen of Bordetella bronchispetica. Active immunization using this antigen in incomplete Freund adjuvant or Alhydrogel is taught, see top of page 758, column 1. The reference teaches that

Art Unit: 1645

B.bronchispetica is a bacterial pathogen associated with respiratory disease in animals. See page 744, column 1. Although Montaraz et al do not specifically recite that the vaccine may be used to protect dogs against B.bronchispetica, The term "vaccine, effective to protect dogs against Bordetella bronchispetica" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The vaccine composition recited by Montaraz et al is structurally identical to that recited in claims 1-5 and 9, and therefore it would be capable of performing the intended use. Although Montaraz et al do not specifically recite the amino acid sequence of their P68 antigen, it would inherently be that set forth in Applicant's SEQ ID NO: 1, given the source, activity, and size, absent specific evidence to the contrary. The amino acid sequence of a known protein is an inherent property and the later elucidation of the amino acid sequence of an already known protein does not impart novelty. Additionally, claim 2 is a product-by-process claim. "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward

Art Unit: 1645

with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). The product claimed is of identical size, has identical function and was obtained from an identical source, accordingly it would be expected to be the same.

Response to Applicant's arguments:

Applicants argue that Montaraz et al used a native p68 protein and do not teach a 'recombinantly produced protein' for use as a vaccine in dogs. Claim 1 is a product-by-process claim, e.g., produced recombinantly. "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). The product claimed is of identical size, has identical function and was obtained from an identical source, accordingly it would be expected to be the same.

Applicants argue that Montaraz et al do not teach the intent to vaccinate dogs which is a limiting feature of claim 1. They argue that a recombinantly produced p68 antigen vaccine 'for dogs' is not taught. Applicants argue that 'vaccine' is not solely a word that adds an element to the claims, but it must

Art Unit: 1645

impart some type of protection to the host. These arguments have been fully and carefully considered but are not deemed persuasive. The product instantly claimed is structurally identical to the product taught by Montaraz et al. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A patent for a new method/use of a known product may be obtained, but a patent cannot be obtained for a known product, e.g., when the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a *process of using*. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) (Claims 1 and 6, directed to a method of effecting nonaddictive analgesia (pain reduction) in animals, were found to be anticipated

Art Unit: 1645

by the applied prior art which disclosed the same compounds for effecting analgesia but which was silent as to addiction. The court upheld the rejection and stated that the applicants had merely found a new property of the compound and such a discovery did not constitute a new use. See also *In re Tomlinson*, 363 F.2d 928, 150 USPQ 623 (CCPA 1966) . "While the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition." 363 F.2d at 934, 150 USPQ at 628 (emphasis in original.).

Further, it is noted that the instant specification allows for the use of both native p68 proteins, i.e., naturally occurring purified or recombinantly produced p68 proteins. See page 7, lines 24-26. Accordingly, the polypeptides in the instant vaccines would be identical to those of the prior art. Lastly, the Experimental Vaccine used in the working examples methods in Example 5 of the instant specification use a native p68 antigen with no mention of the signal peptide being cleaved. Written support for 'lacks the signal sequence' could not be found in the originally filed specification. See written description rejection set forth above.

6. Claims 1, 3, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Novonty et al (*Infection and Immunity*, 1985, 47: 744-751).

Novonty et al teach the isolation of the native P68 antigen of *Bordetella bronchispetica*. Active immunization using this antigen in oil or mineral adjuvant is taught, see page 192, column 2, 2nd paragraph above the "Results". The reference

teaches that *B. bronchispetica* is a bacterial pathogen associated with respiratory disease in animals. See page 190, column 1. Although Novonty et al do not specifically recite that the vaccine may be used to protect dogs against *B. bronchispetica*, The term "vaccine, effective to protect dogs against *Bordetella bronchispetica*" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The vaccine composition recited by Novonty et al is structurally identical to that recited in claims 1-5, and therefore it would be capable of performing the intended use. Although Novotny et al do not specifically recite the amino acid sequence of their P68 antigen, it would inherently be that set forth in Applicant's SEQ ID NO: 1, given the source, activity, and size, absent specific evidence to the contrary. The amino acid sequence of a known protein is an inherent property and the later elucidation of the amino acid sequence of an already known protein does not impart novelty. Additionally, claim 2 is a product-by-process claim. "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with

Art Unit: 1645

evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). The product claimed is of identical size, has identical function and was obtained from an identical source, accordingly it would be expected to be the same.

Response to Applicants' arguments:

Applicants argue that Novotny et al merely evaluate B.bronchiseptica vaccines for pigs and identify that a p68 antigen appears to be an important immunogen of B.bronchiseptica. Further, they argue that the reference does not teach that the polypeptide was recombinantly produced or that the vaccine could be used in dogs. These arguments have been fully and carefully considered but are not deemed persuasive. Novonty et al teach the isolation of the native P68 antigen of Bordetella bronchispetica. Active immunization using this antigen in oil or mineral adjuvant is taught, see page 192, column 2, 2nd paragraph above the "Results". A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A patent for a new method/use of a known product may be obtained, but a patent cannot be obtained for a known product, e.g., when the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. Under the principles of inherency, if a

Art Unit: 1645

prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986).

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) (Claims 1 and 6, directed to a method of effecting nonaddictive analgesia (pain reduction) in animals, were found to be anticipated by the applied prior art which disclosed the same compounds for effecting analgesia but which was silent as to addiction. The court upheld the rejection and stated that the applicants had merely found a new property of the compound and such a discovery did not constitute a new use. See also In re Tomlinson, 363 F.2d 928, 150 USPQ 623 (CCPA 1966) . "While the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition." 363 F.2d at 934, 150 USPQ at 628 (emphasis in original).).

Further, it is noted that the instant specification allows for the use of both native p68 proteins, i.e., naturally occurring purified or recombinantly produced p68 proteins. See page 7, lines 24-26. Accordingly, the polypeptides in the instant vaccines would be identical to those of the prior art. Lastly, the

Experimental Vaccine used in the working examples methods in Example 5 of the instant specification use a native p68 antigen with no mention of the signal peptide being cleaved. Written support for 'lacks the signal sequence' could not be found in the originally filed specification. See written description rejection set forth above.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Charles et al (WO 92/17587), Montaraz et al (Infection and Immunity, 1985, 47: 744-751) or by Novonty et al (Infection and Immunity, 1985, 47: 744-751) in view of Azko et al (EP 0 535 740 A1) and Garcon et al (WO 96/33739) and further in view of Acree et al (US Patent No. 4,567,042).

The teachings of Charles, Montaraz and Novonty et al are set forth above.

Although they teach vaccines comprising the P68 antigen from B.bronchiseptica and an adjuvant. They do not specifically teach that the adjuvant may comprise saponin and a surfactant, more particularly Quil A and cholesterol, nor do the primary references teach a method of protecting dogs against B.bronchiseptica comprising administering to a dog said vaccine.

As one of ordinary skill in the art can see from the primary references, B.bronchiseptica p68 antigen is a well known protein whose relevance in vaccination and protective properties are well documented in the prior art. Azko specifically teaches that dogs are sensitive to infection by B.bronchiseptica and that B.bronchiseptica is the primary etiological agent in infectious canine tracheobronchitis (kennel cough). See last full paragraph at the bottom of page 2. It would have been prime facie obvious to one of ordinary skill in the art that dogs could be one of the many animals to benefit from immunization with the p68 antigen. The vaccines taught in the claims would appear to work as well in canines, as in other animals, e.g., pigs, rabbits, guinea pigs, mice, etc., absent specific evidence to the contrary. Azko specifically teaches the use of saponin as a possible adjuvant for B.bronchiseptica vaccines. See page 3, lines 42-44 and 56-57). Garcon et al teaches the use of saponins and cholesterol as an adjuvant and lists antigens from B.bronchiseptica as possible applications for the saponin-cholesterol adjuvant (page 3, lines 19-20). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the adjuvant used in any of the primary references with saponin, such as Quil A, and cholesterol since the prior art (Azko and Garcon) teach these adjuvants worked well in vaccines comprising B.bronchiseptica antigens.

Response to Applicants' arguments:

Applicants argue that none of the primary references teach methods of protecting dogs against B.bronchiseptica using the known vaccines comprising isolated and purified p68 antigen (either recombinant or native). They argue that vaccines from other

Art Unit: 1645

animal strains, i.e., porcine strains, performed poorly against challenge by canine strains. This has been fully and carefully considered but is not deemed persuasive. The instant claims are not to vaccines comprising strains, but are drawn to vaccines comprising an isolated and purified protein from *B.bronchispetica*. The prior art teaches its use in veterinary vaccines, particularly animals known to be susceptible to *B.bronchispetica* infection. As one of ordinary skill in the art can see from the primary references, *B.bronchiseptica* p68 antigen is a well known protein whose relevance in vaccination and protective properties are well documented in the prior art. Azko specifically teaches that dogs are sensitive to infection by *B.bronchiseptica* and that *B.bronchiseptica* is the primary etiological agent in infectious canine tracheobronchitis (kennel cough). See last full paragraph at the bottom of page 2. It would have been prime facie obvious to one of ordinary skill in the art that dogs could be one of the many animals to benefit from immunization with the p68 antigen. The vaccines taught in the claims would appear to work as well in canines, as in other animals, e.g., pigs, rabbits, guinea pigs, mice, etc., *absent specific evidence to the contrary*. Applicants have not provided unexpected results in declaratory form or other form. As stated above, the protein contained in the vaccine compositions which is taught in the primary references is structurally identical to the protein instantly claimed. The arguments regarding 'recombinant production' were addressed in the response to the arguments to the 102 rejections above.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

Art Unit: 1645

combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, As one of ordinary skill in the art can see from the primary references, B.bronchiseptica p68 antigen is a well known protein whose relevance in vaccination and protective properties are well documented in the prior art. Azko specifically teaches that dogs are sensitive to infection by B.bronchiseptica and that B.bronchiseptica is the primary etiological agent in infectious canine tracheobronchitis (kennel cough). See last full paragraph at the bottom of page 2. It would have been prime facie obvious to one of ordinary skill in the art that dogs could be one of the many animals to benefit from immunization with the p68 antigen.

Prior Art Previously Made of Record, not relied on:

- A) Novotny et al Infect. Immun. Oct. 1985, 50(1): 199-206. Novotny et al. teach the isolation of a 68K outer membrane protein from B.bronchispetica with adenylate cyclase activity. However, they do not specifically recite that an adjuvant was used.
- B) Kobisch et al Infect. Immun. Feb. 1990, 58(2): 352-357. Novotny et al. teach the isolation of a 68K outer membrane protein from B.bronchispetica with adenylate cyclase activity. However, they do not specifically recite that an adjuvant was used.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1645

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

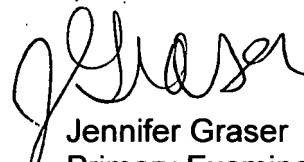
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.


Jennifer Graser
Primary Examiner
Art Unit 1645
5/19/07